Exhibit 7

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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ARIA DIAGNOSTICS, INC. Plaintiff, v. SEQUENOM, INC., Defendant/ Counterclaim-Plaintiff, v. ARIA DIAGNOSTICS, INC., Counterclaim-Defendant, and ISIS INNOVATION LIMITED, Nominal Counterclaim-Defendant.	Case No. 3:11-cv-06391-SI **NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION** Date: April 13, 2012 Time: 9:00 a.m. Place: Courtroom 10, 19th Floor

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NOTICE OF MOTION AND MOTION

On April 13, 2012, at 9:00 a.m., or as soon thereafter as the matter may be heard, before the Honorable Susan Illston in Courtroom 10, 19th Floor, 450 Golden Gate Avenue, San Francisco, California, Defendant and Counterclaim-Plaintiff Sequenom, Inc. ("Sequenom") will and hereby does move for an order for a preliminary injunction pursuant to Fed. R. Civ. P. 65(a) restraining and enjoining Plaintiff Aria Diagnostics, Inc. ("Aria"), its officers, agents, servants, employees, and attorneys, and all those in acting in concert or participating with them:

1. From making, using, selling, offering for sale, or importing into the United States any product or service utilizing the method of Claim 1, 2, 8, 19-22, 24 or 25 of U.S. Patent No. 6,258,540; and

2. Specifically, and without limiting the preceding paragraph, from making, using, selling, offering for sale, or importing into the United States the Harmony Prenatal Test™.

This motion is made on the grounds and presents the following issues to be decided:

1. Sequenom is likely to succeed on the merits of its claims that Aria is infringing Claims 1, 2, 8, 19-22, 24 and/or 25 of U.S. Patent No. 6,258,540;

2. Sequenom likely will sustain immediate and irreparable injury unless the activities described above are enjoined pending a final determination of the merits of this action at trial or otherwise;

3. The balance of equities tips in favor of Sequenom because the harm that will be suffered by Sequenom if a preliminary injunction is not granted outweighs any harm that may be imposed on Aria by the granting of a preliminary injunction; and

4. The granting of the requested preliminary injunction is in the public interest.

Sequenom's motion is based on this Notice of Motion and Motion, the attached opening memorandum of points and authorities, the accompanying declarations of Dr. Mark I. Evans, William Welch, Dereck Tatman, Dr. Mohan Rao, and Michael J. Malecek, and the accompanying proposed order.

MEMORANDUM OF POINTS AND AUTHORITIES

Sequenom submits this memorandum in support of its motion to preliminarily enjoin Aria from infringing Sequenom's in-licensed U.S. Patent No. 6,258,540 ("the '540 patent") pending a final determination of this case at trial or otherwise. Sequenom is an innovator in the noninvasive prenatal DNA diagnosis market. It holds an exclusive license to the foundational patent in the field – the '540 patent – and recently launched its MaterniT21™ test based on that patent. Aria plans to launch a test that infringes the '540 patent and, if not enjoined, would compete directly with Sequenom's MaterniT21 test. Aria plans to compete on price with its infringing test, and thus Aria seeks not only to trample over Sequenom's patent rights but also to cruise into the marketplace that Sequenom has created from scratch through innovation and huge investments of time, talent, and money.

Sequenom has established each prerequisite for an order preliminarily enjoining Aria's impending commercial launch of a prenatal test that infringes the '540 patent, as demonstrated in detail in the accompanying declarations of Dr. Mark I. Evans, a renowned prenatal diagnosis expert, William Welch, Sequenom's Senior Vice President of Diagnostics, Dereck Tatman, Sequenom's Vice President of Business Development, and Dr. Mohan Rao, an expert economist. Absent preliminary injunctive relief, Sequenom will be irreparably harmed and deprived of the opportunity to exploit fully its exclusive patent rights and to use its patented technology to develop the market for its new noninvasive prenatal test for fetal chromosomal defects.

I. STATEMENT OF FACTS AND SUMMARY OF ARGUMENT

A. Sequenom's Revolutionary New Product And The Importance Of Exclusivity

Sequenom is a San Diego-based company committed to improving healthcare through revolutionary genetic analysis solutions. (Welch Decl. ¶¶ 5-6.) Sequenom's "flagship" product is its innovative noninvasive prenatal test – the MaterniT21 test – which detects Down syndrome and other chromosomal abnormalities (or "aneuploidies") in the fetus. (*Id.* ¶ 9.) Down syndrome

is caused by an extra copy of chromosome 21 ("trisomy 21").[1] The MaterniT21 test also detects Edwards syndrome ("trisomy 18") and Patau syndrome ("trisomy 13"). (*Id*. ¶ 8.)[2] The MaterniT21 test will ultimately change the standard of care for prenatal diagnosis because it detects fetal aneuploidies without engaging in the conventional invasive procedures such as amniocentesis and chorionic villus sampling ("CVS") that pose a risk to fetus and mother. (*Id*. ¶¶ 10-11). With the commercial launch of the MaterniT21 test in October 2011, Sequenom was the first company to market a noninvasive prenatal diagnostic test for Down syndrome or any other fetal aneuploidy. (*Id*. ¶ 9.) The MaterniT21 test will establish Sequenom as the leader in the new market for noninvasive prenatal diagnostic tests for fetal aneuploidies. (*Id*.)

The MaterniT21 test uses the inventions of the '540 patent, which Sequenom has exclusively in-licensed from Isis Innovation Limited ("Isis"), the technology transfer company of the University of Oxford. (Tatman Decl. ¶¶ 6-7.) Sequenom has committed significant resources to developing and commercializing its MaterniT21 test. (Welch Decl. ¶¶ 36-43, 60; Tatman Decl. ¶ 17.) Sequenom's business plan for marketing the MaterniT21 test relies on its having exclusive rights to the technology embodied in the '540 patent. (Welch Decl. ¶¶ 9-10, 15-26, 36-43, 49; Tatman Decl. ¶¶ 6-7, 17-18.)

The market for the MaterniT21 test is new. (Welch Decl. ¶ 15.) Sequenom is pioneering this new market, which involves persuading physicians – in particular Maternal Fetal Medicine Specialists and OB/GYNs – of the clinical utility and benefits of the MaterniT21 test, as adoption of the test by key opinion leaders will gradually change the standard of care from the current invasive procedures (amniocentesis or CVS) to the noninvasive MaterniT21 test. (*Id*. ¶¶ 16-20, 24, 59.) To promote market adoption, Sequenom must manage a complicated market of doctors, patients and insurance coverage providers, each with varying incentives. (Welch Decl. ¶¶ 16, 27-

[1] "Aneuploidy" is having an abnormal chromosome count, and usually involves a change in the amount of a single chromosome. (Evans Decl. ¶ 28.) "Trisomy" is an aneuploidy in which there are three copies of a chromosome, rather than the normal two. (*Id*. ¶ 28.)

[2] In February 2012, Sequenom expanded the application of the MaterniT21 test to include detection of fetal trisomies 18 and 13 (and concurrently rebranded the test from MaterniT21™ to MaterniT21 PLUS™). (Welch Decl. ¶ 8.)

35; Rao Decl. ¶¶ 21-27, 31.) Sequenom has actively progressed the rollout of the MaterniT21 test since its launch five months ago. (Welch Decl. ¶¶ 15-26.) The MaterniT21 test is now available in all 50 states, and Sequenom is targeting a total of 7,500 physicians with high volume practices, representing substantially all of the accessible market. (*Id*. ¶ 20.)

Sequenom has expended considerable resources to develop and clinically validate the MaterniT21 test, having spent on the order of $70 million in research and development and other pre-launch expenses. (*Id*. ¶ 41.) To properly manage this new and complex market, Sequenom projects that its investment in the ongoing launch of the MaterniT21 test will exceed another $70 million in 2012. (*Id*. ¶ 42.) In the few months since launch, Sequenom already has doubled its sales force, increasing from 22 to 44 active field sales representatives, and is prepared to expand to 80 active field representatives as appropriate to accommodate market expansion. (*Id*. ¶ 21.)

Sequenom also has made substantial investment in its San Diego laboratory, which currently has the capacity to conduct approximately 100,000 tests annually, more than enough to serve even the most optimistic views of the potential uptake of the test in 2012. (*Id*. ¶¶ 22-26.) Sequenom is increasing the capacity of its San Diego laboratory and is building out another laboratory in North Carolina, which will enable Sequenom to fully serve 100% of the demand for noninvasive tests for fetal aneuploidies in 2012, 2013, and beyond. (*Id*. ¶ 26.)

Market exclusivity is important to success in these types of emerging markets for diagnostic tests, where market price is governed by insurance reimbursement payors. Sequenom holds the exclusive license to the '540 patent for all fields of use in the United States, and its policy and intention is to be the exclusive purveyor of noninvasive tests using cell-free fetal DNA to detect fetal aneuploidies in the United States.[3] (Tatman Decl. ¶¶ 7, 16.) Aria's infringing entry into the market would irreparably harm Sequenom's business and business strategy. (Welch Decl. ¶¶ 48-56, 59-61; Rao Decl. ¶¶ 28-34, 35-38, 39-45.)

[3] Sequenom's policy is that it will consider granting sublicenses to others (1) in fields outside of noninvasive tests for detection of fetal aneuploidies and (2) in the field of noninvasive tests for detection of fetal aneuploidies outside of the United States. (Tatman Decl. ¶ 15.)

B. Noninvasive Prenatal Diagnostic Testing For Aneuploidy: A Revolution In Prenatal Care Enabled By The Ground-Breaking '540 Invention

The technology at issue in this case underlying both the MaterniT21 test and Aria's infringing test is noninvasive prenatal nucleic acid testing for aneuploidy by analysis of cell-free fetal DNA that is present in the mother's blood plasma. This new technology is a dramatic improvement over the current standard of care because it is noninvasive, which means that the test can be done by the examination of fetal nucleic acids present in a blood sample drawn from the mother. (Evans Decl. ¶¶ 36-37.) This is a departure from the current standard of care which, for women with advanced maternal age (>35) or other risk factors (*e.g.*, family history), requires an invasive procedure such as amniocentesis or CVS. (*Id.* ¶¶ 31, 36-27.)

Because both amniocentesis and CVS are "invasive" procedures – requiring an insertion into the mother's body close to the fetus – there is an inherent, although small, risk of miscarriage. (*Id.* ¶¶ 36-37.) Given the risks of invasive prenatal testing, developing a noninvasive test to replace invasive testing has been a long-held goal in the prenatal diagnosis field. (*Id.* ¶¶ 37-38.) Use of noninvasive procedures avoids this risk to the fetus and mother. (*Id.* ¶¶ 36-38.) The methods claimed by the '540 patent for detecting a paternally inherited nucleic acid of fetal origin from a maternal serum or plasma sample are the very foundation for these noninvasive tests for prenatal aneuploidies. (*Id.* ¶¶ 41, 57.)

Around 1996-1997, Drs. Dennis Lo and James Wainscoat, who had been working in the field of prenatal diagnosis for many years, discovered that fetal DNA is detectable in maternal serum or plasma samples. (*Id.* ¶ 45.) This was a landmark discovery. (*Id.*) Dr. Lo has received widespread recognition for this ground-breaking invention, and for, as the Royal Society[4] described it, "creating a paradigm shift in non-invasive prenatal diagnosis." (*Id.* ¶¶ 46-53.)

Previously, researchers had focused efforts on detecting fetal cells because no one knew there was cell-free fetal DNA in maternal plasma. (*Id.* ¶¶ 39-41.) Drs. Lo and Wainscoat's discovery of cell-free fetal DNA in maternal plasma has been described by other researchers in

[4] The Royal Society is "made up of the most eminent scientists, engineers and technologists from the UK and the Commonwealth." (Evans Dec. ¶ 46.)

the field as "one of the most exciting discoveries made in recent years." (*Id.* ¶ 71.) The discovery laid the foundation for an entirely new method of noninvasive prenatal diagnosis. (*Id.* ¶ 41.)

In addition to scientific accolades, Drs. Lo and Wainscoat were awarded the '540 patent for their invention. The '540 patent specification explains that "prenatal diagnosis" as used in the patent "covers determination of any maternal or foetal condition or characteristic which is related to either the foetal DNA itself or to the quality or quantity of the foetal DNA in the maternal serum or plasma." (*Id.* ¶ 61.) This includes "detection of foetal abnormalities which may be for example chromosomal aneuploidies or simple mutations." (*Id.*) The specification then explains how to perform the invention, and describes a quantitative approach for detecting fetal nucleic acid and hence aneuploidy. (*Id.* ¶¶ 62-67.) The specification describes that "[t]he plasma or serum-based non-invasive prenatal diagnosis method according to the invention can be applied to screening for Down's Syndrome and other chromosomal aneuploidies." (*Id.* ¶ 64.) Detailed analysis demonstrating that Aria's Harmony Prenatal Test infringes the '540 patent is set forth in the declaration of Dr. Evans at paragraphs 80-145.

C. Aria's Imminent Launch Of An Infringing Test

In January 2012, Aria, a small private company previously operating under the name Tandem Diagnostics, came out of "stealth" mode and announced its plans to commercialize a test to compete with Sequenom. (Welch Decl. ¶ 44.). In a January 9, 2012 press release, Aria announced that it "is developing a directed approach to cell-free DNA (cfDNA) analysis in maternal blood to create a safe, highly accurate and affordable test for pregnant women." (Welch Decl. ¶ 57, Exh. 13.) In this same press release, Aria announced that it would use recently obtained investor funds "to support product development and prepare commercialization of its proprietary prenatal test to detect common fetal trisomies such as Trisomy 21 . . . ." and "is currently conducting clinical studies to evaluate the performance of its blood test in detecting fetal chromosomal conditions in pregnant women, with the first peer-reviewed data on the test published online Jan. 6, 2012 in *Prenatal Diagnosis*." (*Id.*)

In three January publications, Aria disclosed the technical details of how its test would work. (Evans Decl. ¶ 87.) Those publications made it abundantly clear that Aria's technology infringes the '540 patent. On February 6, 2012, Aria announced in a press release that the commercial name for its infringing test would be "Harmony Prenatal Test™." (Welch Decl. ¶ 46, Exh. 11.) At the Maternal-Fetal Medicine Society's 32nd Annual Meeting, held from February 6-11, 2012, Aria announced the introduction of its infringing test. (Welch Decl. ¶ 47.) Aria also made statements to conference participants indicating that it would offer its test at a price of $900, which is one-third of MaterniT21's list price of $2,762. (*Id.* ¶¶ 30, 47.)[5]

II. ARGUMENT

The Patent Act expressly authorizes district courts to grant preliminary injunctive relief "in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. A plaintiff "seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *AstraZeneca LP v. Apotex*, 633 F.3d 1042, 1049 (Fed. Cir. 2010) (affirming grant of preliminary injunction).[6] As shown below, Sequenom has satisfied each prerequisite for entry of a preliminary injunction enjoining Aria's infringement of the '540 patent.

A. Sequenom Is Likely To Succeed On Its Patent Infringement Claims

To establish likelihood of success on the merits, Sequenom must show that (1) it will likely prove infringement of one or more claims of the '540 patent and (2) the infringed claims will likely withstand Aria's challenges to validity. *See, e.g.*, *Sanofi-Synthelabo v. Apotex, Inc.*,

[5] Sequenom's understanding that $900 is the "list price" of Aria's Harmony Prenatal Test is based on what Mr. Welch heard at the Maternal-Fetal Medicine Society annual meeting. Sequenom is not aware of any written material that sets forth the list price of Aria's test, and thus it is not entirely clear if $900 (or some other amount) is the list price.

[6] Because a motion for preliminary injunction, "although a procedural matter, involves substantive matters unique to patent law," Federal Circuit law governs the standard for its grant. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988).

470 F.3d 1368, 1374 (Fed. Cir. 2006). Whether the plaintiff has made an adequate showing is viewed through the lens of the "presumptions and burdens that will inhere at trial on the merits." *Id*. That lens is significant because "a patent is presumed valid, and this presumption exists at every stage of the litigation." *Id*. at 1375; *see also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1358 (Fed. Cir. 2008) ("At the preliminary injunction stage the district court's claim construction is reviewed, as for other legal issues, for the likelihood of correctness of the ruling. This likelihood is based on the underlying facts as found at this stage of the proceedings, recognizing that 'the burdens at the preliminary injunction stage track the burdens at trial.'") (affirming preliminary injunction); *H.H. Robertson, Co. v. United Steel Deck, Inc*., 820 F.2d 384, 390 (Fed. Cir. 1987) ("The grant of a preliminary injunction does not require that infringement be proved beyond all question, or that there be no evidence supporting the viewpoint of the accused infringer;" rather, plaintiff only needs to show a "reasonable probability" of prevailing on its claim for patent infringement to warrant a preliminary injunction), *overruled on other grounds, Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

As summarized below and described in detail in Dr. Evans' declaration, Sequenom has established conclusively that Aria's Harmony Prenatal Test infringes multiple claims of the '540 patent. As to the second prong of the likelihood of success standard, a patent is presumed valid, and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. The presumption may be rebutted only by "clear and convincing evidence" of invalidity. *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). When a patentee moves for a preliminary injunction, the defendant has the burden to introduce persuasive evidence of invalidity. Only then does the patentee need to rebut the challenge by showing that the defense lacks substantial merit. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339-40 (Fed. Cir. 2003). Sequenom will address any invalidity arguments if and when raised. Notably, Aria has yet to even allege that the '540 patent is invalid.

As shown below, Sequenom is likely to succeed in establishing that Aria infringed the '540 patent, and Sequenom also is likely to succeed on the merits in rebutting any challenges by Aria to the validity of the '540 patent.

1. Aria Infringes The '540 Patent

As described in more detail in the declaration of Dr. Mark Evans, Aria's Harmony Prenatal Test infringes the '540 patent by (1) amplifying paternally inherited nucleic acids from the fetus that are present in the serum or plasma of a pregnant mother and, (2) detecting the presence of those nucleic acids. As described in Aria's three January 2012 publications and press releases, Aria's method meets each and every limitation of all three of the independent claims of the '540 patent – Claims 1, 24, and 25 – and at least the following dependent claims: 2, 8, and 19-22. (Evans Decl. ¶¶ 86-145, Exhs. 5-8.)

Claim 1 reads as follows:

> A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
>
> amplifying a paternally inherited nucleic acid from the serum or plasma sample and
>
> detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

(a) The Claim Language Has Its Common And Ordinary Meaning

All of the words in the claims of the '540 patent, including Claim 1, have their common and ordinary meaning to one of skill in the art and, in fact, are generally understandable even to an educated lay person. (Evans Decl. ¶ 90.) Our 3 billion base-pair genome is made of DNA – **D**eoxyribose **N**ucleic **A**cid. (*Id.* ¶ 26.) A "nucleic acid" is simply a sugar and phosphate backbone with a string of bases (A, T, G, and Cs). (*Id.*) A "paternally inherited nucleic acid of fetal origin" is a nucleic acid that originates from the fetus and is inherited from the father. (*Id.* ¶ 93.) A fetus inherits almost exactly half of its DNA from the father. (*Id.* ¶ 26.) To "detect" a nucleic acid means the same thing it means in everyday ordinary language, that is, to discover or determine the existence, presence, or fact of it. (*Id.* ¶¶ 94, 104.)

"Amplifying" a nucleic acid likewise has its everyday meaning, that is, to increase the amount of the nucleic acid by making copies of it. (*Id.* ¶ 98.) A variety of common methods of amplifying nucleic acids are referenced in the patent, including perhaps the most-widely used, polymerase chain reaction ("PCR"). (*Id.* ¶ 98.) Finally, a "maternal serum or plasma sample" is

a sample of a portion of blood taken from the mother; the liquid, non-cellular portion made of water, salts, and protein is called "plasma," and when plasma's clotting factors are removed, it is called "serum." (*Id*. ¶ 96.) With these straightforward understandings of the claim terms, it is abundantly clear that Aria's Harmony Prenatal Test infringes the claims of the '540 patent, including exemplary Claim 1.

(b) The Harmony Prenatal Test Is Performed On A Maternal Serum Or Plasma Sample Of A Pregnant Female

As Aria has stated, the test "is a directed noninvasive approach to cell-free DNA (cfDNA) analysis in maternal blood to detect common trisomies linked to genetic disorders. . . [that] couples innovative biochemistry, DANSR™, and a proprietary algorithm, FORTE™, to efficiently analyze patients' blood samples." (*Id*. ¶ 97, Exh. 8.) As described in more detail in the Aria AJOG publications, a blood sample is collected from the pregnant mother, plasma is isolated from the blood, and cfDNA is isolated from plasma. (Evans Decl. ¶¶ 96-97, 100, Exh. 6 at 7.)

(c) The Harmony Prenatal Test Amplifies Paternally Inherited Nucleic Acids From The Sample

At a number of sites (or "loci") on the genome, Aria next hybridizes short chains of nucleotides (called "oligonucleotides") to the cfDNA sample to create a copy of those sites. Aria then makes many more copies of this first copy by amplifying it using PCR. (Evans Decl. ¶¶ 98-103, Exh. 6 at 6-7, Fig. 1.) The nucleic acid from the fetus is made up of nucleic acid inherited from both the father and the mother. Therefore, the amplified nucleic acid contains "paternally inherited nucleic acid of fetal origin." (Evans Decl. ¶ 101.) The amplified nucleic acids will also include (1) maternally inherited nucleic acids of fetal origin, and (2) nucleic acids of the mother herself. (*Id*. ¶¶ 101-102.)

(d) The Harmony Prenatal Test Detects Paternally Inherited Nucleic Acids From The Sample

All of the amplified nucleic acids are then sequenced and identified. (*Id*. ¶¶ 104-106.) The amplified sample is put on a sequencing machine that reads out a "56 base locus-specific sequence." (*Id*. ¶ 105.) By comparing this sequence to the expected locus sequence, Aria assigns each such sequence to a specific chromosome. (*Id*. ¶¶ 105-106, Exh. 6 at 7.) At non-

polymorphic sites – *i.e.*, where the fetal DNA and maternal DNA have the same sequence – Aria uses quantitative methods to determine if the fetus has two copies of chromosome 21 (one paternally inherited and one maternally-inherited) or three copies of chromosome 21 (one paternally inherited, one maternally inherited, and one inherited either from the mother or the father). (*Id.* ¶¶ 104-113.) Whether two or three copies of chromosome 21 are detected, the Aria test detects the paternally inherited copy of chromosome 21. (*Id.* ¶¶ 104-113.) At polymorphic sites, Aria specifically detects nucleic acid sequences where the paternally inherited nucleic acid differs from the maternal nucleic acid or, as Aria expresses it, "where fetal alleles differ from maternal alleles." (*Id.* ¶¶ 110-113, Exh. 6 at 8.) Because the fetus inherits its nucleic acid sequences from the mother and the father, the fetal alleles that differ from maternal alleles will exist on a nucleic acid inherited from the father. (*Id.* ¶ 111.)

(e) Other Infringed Claims

Determining infringement of other claims is a simple iteration of the above analysis with the additional elements covered. For example, dependent claim 2 requires that the amplification step be performed by PCR. Aria's amplification step is performed by PCR. (*Id.* ¶¶ 115-117.) Thus, Aria infringes claim 2. Dependent claim 8 requires that "the presence of a foetal nucleic acid from a paternally-inherited non-Y chromosome is detected." (*Id.* ¶¶ 118-120.) The Y chromosome is the sex chromosome that is only present in male fetuses. (*Id.*) As described above and in more detail in Dr. Evans' declaration, Aria's assays amplify and detect nucleic acids that are paternally inherited that are not on the Y-chromosome. (*Id.*) Given the page constraints, Sequenom respectfully refers the Court to Dr. Evans' declaration for a full analysis of these issues as well as the support for infringement of claims 19-22, 24, and 25. (*Id.* ¶¶ 121-145.)

2. Aria Bears A Heavy Burden To Overcome The Presumption Of Validity

The presumption of validity of a patent applies at all stages of the litigation, including in the context of a preliminary injunction. *See* 35 U.S.C. § 282; *Sanofi*, 470 F.3d at 1375. Absent a persuasive showing of invalidity by Aria, the statutory presumption alone establishes a likelihood of success on the issue of validity. *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d

1085, 1088 (Fed. Cir. 1998) (holding that "where the challenger fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies the patentee's burden on the validity issue."); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001) (same).

Thus, Sequenom need not affirmatively *prove* patent validity to show a likelihood of success on the merits. *If* Aria can raise a question of validity, then Sequenom must only show that the defense lacks substantial merit. *Oakley*, 316 F.3d at 1339-40. That determination must be viewed through the prism of the ultimate "clear and convincing" standard applicable to invalidity defenses. *See Microsoft*, 131 S. Ct. at 2242.

Notably, despite being well aware of the importance of the '540 patent to this field, Aria has been unable to make even an allegation of invalidity sufficient to meet the Rule 11 standard. Before Aria emerged from stealth mode, Sequenom sent a letter on December 6, 2011, inquiring of Aria's (then Tandem Diagnostics) plans. (Declaration of Michael J. Malecek in Support of Motion for Preliminary Injunction ("Malecek Decl.") ¶ 2, Exh. 1.) Aria did not respond to that letter, but rather on December 19, 2011, Aria filed a declaratory judgment action in the Northern District of California. (*Id.* ¶ 3, Exh. 2.) In its complaint, Aria did not seek a declaration that the '540 patent was invalid. (*Id.*)

Furthermore, even as of February 8, 2012, Aria's attorneys represented to this Court that they were still in need of time to investigate whether or not they could even allege that the '540 patent was invalid. In their opening brief in support of an *ex parte* motion for an extension of time to respond to the Sequenom's complaint in the instant action, Aria's attorneys stated: "Aria's complaint in the Northern District of California seeks a declaration of non-infringement only. Aria's defenses to the complaint in the instant action likely will include other defenses, such as invalidity of the patent, and Aria requires additional time to investigate those defenses." (*Id.* ¶ 4, Exh. 3.) In its February 8, 2012 reply, Aria stated: "Aria needs time to investigate and formulate its defenses to Sequenom's affirmative infringement allegations, including in particular defenses based on invalidity of the '540 patent." (*Id.* ¶ 5, Exh. 4.)

Aria will not be able to establish that the claims would be obvious to one of ordinary skill in the art under the clear and convincing standard. Any attempt by Aria to do so will be driven by impermissible hindsight. The public record is clear that scientists in the field at the time – the people of ordinary skill in the art to whom the obviousness inquiry is directed – understood and acknowledged the exciting, inventive, and non-obvious nature of Dr. Lo's invention. (Evans Decl. ¶¶ 53, 71.) Other researchers in the field called it "one of the most exciting discoveries made in recent years," and an "exciting discovery." (*Id*. ¶ 71.) Dr. Lo has received extensive scientific honors for this discovery. (*Id*. ¶¶ 46-48, 52.) Further, any validity challenge involving references considered by the USPTO will be "especially difficult." *Sanofi*, 470 F.3d at 1375 (upholding preliminary injunction).

B. Sequenom Is Likely To Suffer Irreparable Injury If Aria's Patent Infringement Is Not Preliminarily Enjoined

As the Supreme Court recently emphasized, "[o]ur frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis by the Court). *Accord AstraZeneca*, 633 F.3d at 1049 (affirming preliminary injunction enjoining patent infringement).

Absent a preliminary injunction, the irreparable harm to Sequenom would include price erosion, loss of market share, loss of profits, loss of goodwill, harm to the Sequenom's reputation as technology innovator and market leader, and damage to its ability to raise capital to fund further research or business opportunities. (Welch Decl. ¶¶ 44-61; Rao Decl. ¶¶ 28-34, 35-38, 39-45.) These types of irreparable harm justify preliminary injunctive relief. *See, e.g.*, *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (affirming grant of preliminary injunction and holding: "Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."); *Research Found. of St. Univ. of N.Y. v. Mylan Pharms. Inc.*, 723 F. Supp. 2d 638, 646 (D. Del. 2010) (granting preliminary injunction on evidence of price erosion, loss of market share, loss of profits, loss of research opportunities, and possible layoffs).

These types of irreparable harm are especially likely when, as here, the accused infringer is a direct competitor: "direct competition in a marketplace weighs heavily in favor of a finding of irreparable injury" and courts "routinely" find irreparable harm where "the infringer and the patentee are direct competitors." *Mass Eng'r Design, Inc. v. Ergotron, Inc.*, 633 F. Supp. 2d 361, 393 (E.D. Tex. 2009); *see also, e.g., Fresenius Med. Care Holdings, Inc. v. Baxter Int'1, Inc.*, 2008 WL 928496, at *3 (N.D. Cal. Apr. 4, 2008) (granting permanent injunction, noting that "the principal value of a patent is the right to exclude arch competitors from making, selling and using an infringing product."), *aff'd in part, rev 'd in part and vacated in part on other grounds*, 582 F.3d 1288, 1302-03 (Fed. Cir. 2009).

The likelihood of these types of irreparable harm is further heightened when, as here, the market is new and developing. As the Federal Circuit stated earlier this year:

> During the growth stage of a product it is particularly crucial to be able to distinguish oneself from competitors. This includes building the brand, expanding the customer base, and establishing one's reputation and leadership in the market.

Celsis, 665 F.3d at 931 (affirming the district court's "finding that Celsis would suffer irreparable harm absent a preliminary injunction").

As demonstrated below, if Aria is not enjoined, Aria will utilize the inventions of the '540 patent to compete in the same market as Sequenom – a market that Sequenom is creating from scratch – and cause irreparable harm to Sequenom.

1. The Accused Aria Harmony Prenatal Test, If Not Enjoined, Would Compete Directly With Sequenom's MateriT21 Test

With its revolutionary and pioneering MateriT21 test, Sequenom is creating the market for noninvasive tests for fetal aneuploidies. (Welch Decl. ¶¶ 9-11, 15-26; Tatman Decl. ¶ 4-5.) The MateriT21 test is Sequenom's flagship offering – it is the most significant and valuable product or service that Sequenom has on the market – and it is the core of Sequenom's business. (Welch Decl. ¶¶ 49-50.) Sequenom's strategic plan is to reserve solely for itself the exclusive right to offer for sale and sell noninvasive prenatal tests that use its patent-protected technology for detection of fetal aneuploidies in the United States market. (Tatman Decl. ¶ 14; Welch Decl. ¶ 51.) Sequenom has paid Isis millions of dollars for an exclusive license to the '540 patent.

(Tatman Decl. ¶ 17). *See Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) ("By entering into an exclusive license agreement, [plaintiff] has manifested a strong interest in maintaining an exclusive position in the relevant market.").

Absent a preliminary injunction, Aria will utilize the inventions of the '540 patent to compete directly against Sequenom in the market that Sequenom is creating from scratch with its patent-protected technology. (Welch Decl. ¶¶ 15-26, 48-56, 59-61.) Injunctive relief is particularly suited to cases where, as here, the plaintiff practices the invention, the defendant is a direct competitor, and the plaintiff's patented technology is the core of its business. As one court put it, "[i]ntellectual property enjoys its highest value when it is asserted against a direct competitor in the plaintiff's market." *Visto Corp. v. Seven Networks, Inc.*, 2006 WL 3741891, *4 (E.D. Tex. Dec. 19, 2006) (granting preliminary injunction, finding irreparable harm caused by infringing competitor even when a third party holds large market share). A "head-to-head competitor . . . has a right . . . not to assist its rival with the use of proprietary technology." *Novozymes A/S v. Genecor Int'1, Inc.*, 474 F. Supp. 2d 592, 613 (D. Del. 2007) (granting permanent injunction). Put simply, the law favors the plaintiff's "right to the full value of its property, particularly the ability to keep it out of its main competitor's hands. Indeed, the principal value of a patent is the right to exclude arch competitors from making, selling and using an infringing product." *Fresenius*, 2008 WL 928496, at *3 (citation omitted).

2. Sequenom Likely Will Suffer Irreversible Price Erosion If Aria Is Not Preliminarily Enjoined

The likelihood of price erosion justifies granting preliminary injunctive relief, particularly when, as here, the price erosion is likely to be irreversible. It is straightforward that "the fact that [the infringer] offers a similar product inevitably weakens [the patentee's] negotiating position with its customers. It is also unlikely that [the patentee] will simply be able to raise its price back to where it would have been if it ultimately prevails in the lawsuit." *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, 714 F. Supp. 2d 919, 936 (E.D. Wis. 2010), *aff'd in relevant part, vacated in part on other grounds*, 2011 WL 2161072, at *9 (Fed. Cir. Jun. 1, 2011).

Aria's publicly stated list price for its Harmony Prenatal Test is $900 (Welch Decl. ¶ 47), which is almost 70% lower than Sequenom's list price of $2,762 for its MateriT21 test. (*Id*. ¶ 30; Rao Decl. ¶¶ 36-37.) Indeed, Aria's strategy is to compete on price. (Welch Decl. ¶ 45, Exh. 10.) If Aria enters the market with its $900 list price for the accused test, it will severely undercut the price that Sequenom would otherwise be able to command for its MateriT21 test. Sequenom will be forced to accept dramatically lower prices for its testing service to remain price-competitive with Aria's infringing test. (*Id*. ¶¶ 53-54.)

The resulting price erosion is likely to be irreversible. The market price for diagnostic tests is governed by insurance reimbursement rates. (*Id*. ¶ 27-35.) The price that Sequenom is able to charge for the MateriT21 test depends most significantly on the reimbursement rates that Sequenom is able to negotiate with insurance coverage providers. (*Id*. ¶ 53.) In that practical sense, the insurance payors are Sequenom's "customers" for the MateniT21 test. The negotiation with each payor involves working to persuade that payor that the MateriT21 test is medically necessary and that the price is justified, based on qualitative and quantitative health economic factors. (*Id*. ¶ 31.) The negotiation with each payor over reimbursement rates for the MateriT21 test can be expected to take a minimum of one year and more likely two or more years. (*Id*. ¶¶ 29, 32.) Thus, Sequenom's ongoing negotiations with payors will take place during the period of time that this litigation is pending – that is, 2012 through at least 2013. (*Id*. ¶ 48.)

While these negotiations are proceeding, Sequenom has implemented a patient-friendly billing policy for the MateriT21 test, under which the out-of-pocket expense to the patient is no more than $235. (*Id*. ¶ 30.) Sequenom is billing the insurance payors directly, billing at the list price of $2,762 and pursuing reimbursement on a case-by-case basis. (*Id*.)[7] The insurance payor may pay the list price, or more typically, a portion of the list price. (*Id*.) Sequenom then pursues the insurance payor for any outstanding amount, through a negotiation or "appeal" process, with the expectation of receiving additional reimbursement. (*Id*.) This billing and negotiation cycle

[7] For insured patients choosing to pay entirely out-of-pocket (and for uninsured patients), the MateriT21 test price is approximately $1,933. (Welch Decl. ¶ 34.)

can take up to nine months. (*Id.*) At present, the reimbursement rates, payment timing, and interest in contracting vary significantly among the insurance payors. (*Id.* ¶ 32.) This is a dynamic environment. The reimbursement rates will not be firmly established until Sequenom works through the issues with the payors and enters contracts with them. (*Id.* ¶¶ 29, 32.)

If Aria is allowed to enter the market, the dynamics of Sequenom's negotiations with the insurance payors will be dramatically altered. Sequenom will have lost the ability to leverage its exclusivity and the payors will insist on resetting negotiations to account for Aria's offering a competing test at a lower price. (*Id.* ¶ 53.) Because insurance coverage providers have dominant bargaining power and can insist on "take it or leave it" contracts, Sequenom will be forced to accept dramatically lower reimbursement rates. (*Id.* ¶ 54; Rao Decl. ¶ 37.) Once Sequenom is forced to accept lower reimbursement levels in order to compete with Aria's lower priced test, the lower price would be hard to reverse. (Welch Decl. ¶ 55; Rao Decl. ¶ 38.)

Economists refer to this feature of pricing as asymmetric price rigidity. (Rao Decl. ¶ 38.) The concept is straightforward: prices are easy to lower but hard to increase, especially when large purchasers such as insurance companies aggressively negotiate reimbursement rates through contracts. (*Id.* ¶ 38.) Even if Aria is later permanently enjoined after a final determination, and must leave the market, it is highly unlikely that Sequenom would then be able to negotiate higher rates to recapture much, let alone all, of the price Sequenom would have been able to achieve but for Aria's entry in the market in the interim period. (Welch Decl. ¶ 55.)

In *Polymer Technologies, Inc. v. Bridwell*, the Federal Circuit addressed a similar (but less severe) example of price rigidity when it vacated a decision denying a preliminary injunction, holding that a new competitor can contribute to an irretrievable loss of market share and damage to customer relationships:

> Years after infringement has begun, it may be impossible to restore a patentee's (or an exclusive licensee's) exclusive position by an award of damages and a permanent injunction. Customers may have established relationships with infringers. The market is rarely the same when a market of multiple sellers is suddenly converted to one with a single seller by legal fiat. Requiring purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option.

103 F.3d at 975-76.

That analysis applies with even more force in the present case. Insurance payors are even more price sensitive than other types of "customers," and insurers take a much more active role in bargaining with providers over the prices of medical care and diagnostic services. (Welch Decl. ¶ 55; Rao Decl. ¶¶ 21-29, 31.) On top of that, the bargaining power of insurance providers is much greater than ordinary "customers." Therefore, the price rigidity phenomenon in the present case would certainly be even more severe than the Federal Circuit found was sufficient in *Polymer*.

In *Hoffman-La Roche Inc. v. Cobalt Pharmaceuticals Inc.*, the accused infringer had planned an imminent launch of its generic drug and two other competitors were expected to enter the market in the next few months. 2010 WL 4687839, at *11 (D.N.J. Nov. 10, 2010). The court granted the preliminary injunction because third-party payors controlled a substantial portion of the plaintiff's sales, and the new generic entrant would irreversibly alter that reimbursement relationship. *Id.* at *12. The court found that the generic competition would cause the plaintiff to lose its favorable [reimbursement] tier placement, which would be near-impossible to regain. *Id.*[8]

Put simply, "[c]ompetitors change the marketplace." *Polymer*, 103 F.3d at 975. Unless Aria is enjoined from entering the market and competing on price with its infringing test, Sequenom will be deprived of its rightful exclusivity in negotiating reimbursement rates with insurance payors. (Welch Decl. ¶ 51.) This harm is irreparable because it is unlikely that Sequenom "will simply be able to raise its price back to where it would have been if it ultimately prevails in the lawsuit." *Kimberly-Clark Worldwide*, 714 F. Supp. 2d at 936.

3. Sequenom Likely Will Suffer Irretrievable Loss Of Market Share, Goodwill, And Leadership Reputation In This Nascent Market

Sequenom commercially launched the MaterniT21 test just five months ago (in October 2011) as the first noninvasive test for fetal aneuploidies brought to market. (Welch Decl. ¶ 15.) The MaterniT21 test is in the early growth phase in the marketplace. (*Id.* ¶ 50.) This phase is

[8] The Federal Circuit in *Sanofi-Synthelabo* likewise agreed that the presence of a competing product (a generic drug) encourages third party payors to place the innovator product on a less favorable reimbursement tier, thereby requiring consumers to pay a higher co-pay, and deterring them from purchasing the innovator product, which decreases the demand for the innovator product. 470 F.3d at 1382.

generally the time period when a company distinguishes itself from current practices, gains medical trust, expands its customer base, and establishes a leadership reputation in the market. (*Id.*) As the Federal Circuit recently put it, "the growth stage of a product . . . is [a] particularly crucial" time for, among other things, "building the brand" and "expanding the customer base." *Celsis*, 664 F.3d at 931.

The primary customers of the MaterniT21 test are physicians. (Welch Decl. ¶¶ 16, 20.) If the physicians are "sold" on the utility and benefits of this innovative test, then they will recommend the test to their patients. (*Id.* ¶¶ 16-19.) The patients are the end-users of the MaterniT21 test. (*Id.* ¶ 16.) The MaterniT21 test is intended for use in pregnant women who are at increased risk for carrying a fetus with Down syndrome or trisomies 18 and 13 – that is, women who will be over age 35 at term or have other clinical indications of high risk. (*Id.* ¶ 13.)

There are approximately 4.3 million births in the United States annually. (Rao Decl. ¶ 20.) Of this total, an estimated 750,000 are classified as high-risk pregnancies, with the remaining 3,550,000 classified as low-risk. (*Id.*; Welch Decl. ¶ 13.) The MaterniT21 test is initially being made available for use in high-risk pregnancies only, because the clinical validation studies of the test have been of women in this high-risk group. (Welch Decl. ¶ 13 n.2.) When further clinical validation studies support providing the test to women in the lower-risk group, Sequenom will make its test available for use in the much larger low-risk group.

Because it will take time for physicians to adopt this new, standard-of-care-changing test, the currently accessible market is considerably less than the 750,000 high-risk pregnancies per year. (*Id.* ¶¶ 22-26.) Sequenom's stated goal is to sell 25,000 MaterniT21 tests in 2012, and its optimistic high case for sales of MaterniT21 in 2012 is 60,000 tests. (*Id.* ¶ 22.) The consensus (average estimate) view of eleven market analysts projects sales of 22,135 MaterniT21 tests in 2012, with the highest estimate among the analysts at 45,000 tests. (*Id.* ¶¶ 24, 26.) If Aria is not enjoined from offering and selling its infringing Harmony Prenatal Test, the resulting harm to Sequenom will include loss of sales and market share precisely at the stage when Sequenom is rolling out the MaterniT21 test. (Welch Decl. ¶ 52; Rao Decl. ¶¶ 31-32.)

Each time Sequenom loses an opportunity sell a physician on the MaterniT21 test because that physician has been sold the infringing Harmony Prenatal Test, that lost opportunity results in an exponential loss of sales and market share. This is because each such physician likely would continue to recommend the same test for each of his or her patients, which equates to the loss of hundreds of sales. (Rao Decl. ¶ 23.)[9] Even at this early stage of the market – which is women in the high-risk group only – market analysts have spoken to some early adopters of the test, who indicate that they would expect to use the test with 500 to 600 patients a year. (Welch Decl. ¶ 24, Exh. 3.)

With projected total sales of 45,000 to 60,000 tests on the high end of estimates, even a small loss of sales to physicians has dramatic effect – for example, the loss of just ten physicians at high volume birthing centers (using the test for 500 to 600 patients a year) would equate to lost sales of as much as 6,000 tests (10 physicians x 600 patients) and a loss of 10% market share, if the market reaches the highest estimate of 60,000. If the market reaches no more than the analysts' consensus view of 22,135, Sequenom's loss of market would be 27%. A loss of market share of between 10% to 27% at this early stage of development of the market would irreparably harm Sequenom. If Aria is not enjoined, it will be "using the patented invention to compete against the patent holder . . . for business in a developing market with a small customer base." *Transocean Offshore Deepwater Drilling, Inc. v. GlobalSantaFe Corp.*, No. H-03-2910, 2006 WL 3813778, at *4 (S.D. Tex. Dec. 27, 2006) (granting injunction) (emphases added).

Other courts likewise have found that such loss of market share in a new and developing market constitutes irreparable harm. As one court put it: "Loss of market share in this nascent market is a key consideration in finding that the Plaintiff suffers irreparable harm – Plaintiff is

[9] Physicians are akin to distributors in that they "distribute" the test to their patients. They are likely to continue to use the first test offered to them. *Cf. Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 2007 WL 5011980, at *7 (N.D. Ga. Feb. 23, 2007) (explaining that where "customers have established relationships with a supplier of infringing products," they are unlikely to switch suppliers and "the patentee is unlikely to be able to begin selling its product at a higher price").

losing market share at a critical time in the market's development, market share it will not have the same opportunity to capture once the market matures." *Tivo, Inc. v. Echostar Commc's Corp.*, 446 F. Supp. 2d 664, 669-670 (E.D. Tex. 2006), *rev'd in part on other grounds*, 516 F.3d 1290 (Fed. Cir. 2008); *see also AstraZeneca*, 633 F.3d at 1061-63 (affirming grant of preliminary injunction where finding of irreparable harm was based on a lack of reliable data on the relevant market, harm to goodwill based on a competitor entering the market (even if it subsequently left), and the potential impact to the plaintiff's workforce from the entry of a competitor); *Celsis*, 665 F.3d at 930 (finding the relevant market was "particularly sensitive because customers buy in bulk and at irregular times, such that the loss of a single sale in this market may be more harmful than for products purchased daily") (emphases added).

Similarly, in *EyeTicket Corp. v. Unisys Corp.*, the court enjoined the defendant from infringing the patent-in-suit where the patentee's technology had tremendous future potential but was not yet widely implemented. 155 F. Supp. 2d 527, 548-49. For that reason, it was difficult to determine the money damages that the patentee would suffer and, in all events, a damages award could not "restore the technological lead-time that the Plaintiff would have enjoyed but for the infringement of the Defendant." *Id*. In *EyeTicket*, as in the present case, the plaintiff "paid for the exclusivity period not only with the hope of generating sales, but in order to establish a reputation for expertise and advanced products . . . ." *Id*. The primary "benefit of the bargain" was "the establishment of a technological lead over its rivals." *Id*.

That is the reality in the present case, too. Sequenom has paid millions of dollars for exclusivity (Tatman Decl. ¶¶ 16-17) and is depending on the exclusivity period provided by the '540 patent to generate sales, establish a reputation for expertise, and maintain a technological lead. (Welch Decl. ¶ 49-51, 56.) Unless Aria is enjoined, Sequenom would be deprived from marketing to physicians that Sequenom is the exclusive purveyor of a noninvasive prenatal test that uses Sequenom's patent-protected technology. (Welch Decl. ¶ 51.) Sequenom would irretrievably lose its "first mover advantage." (Rao Decl. ¶ 28.)

Courts have recognized such harm as irreparable, even in established markets. In *Eli Lilly and Co. v. Teva Pharms. USA, Inc.*, 609 F. Supp. 2d 786 (S.D. Ind. 2009), the accused infringer

voluntarily offered to limit the launch of its generic drug to one million bottles. *Id*. at 810-11. The court rejected that proposal, and held that a limited launch would still cause significant damage because the patentee would no longer maintain marketing exclusivity and would rapidly lose market share and revenue. *Id.* at 811. Such losses would be "difficult, if not impossible" to recover, but even if the patentee could regain its market position, it would suffer irreparable harm in the form of damage to its relationships with physicians and customers, as well as a disruption to its research. *Id.* at 811-12. Those same factors are present here. (Welch Decl. ¶¶ 49-56, 59-61; Rao Decl. ¶¶ 38, 44-45.)

In *Bushnell, Inc. v. Brunton Co.*, the court granted a preliminary injunction against an accused infringer based on the patentee's showing of price erosion, loss of market share, loss of goodwill, and reputational harm. 673 F. Supp. 2d 1241, 1262 (D. Kan. 2009). The patentee lost goodwill in the marketplace, as many customers questioned why the patentee did not match the infringer's price. *Id*. at 1263. Such questions damaged the patentee's "reputation as an innovator and producer of competitively priced quality products" and strained relationships with third parties. *Id.; see also Celsis*, 664 F.3d at 930 (affirming district court finding of irreparable harm of "price erosion, damage to ongoing customer relationships, loss of customer goodwill (*e.g.*, when an effort is later made to restore the original price), and loss of business opportunities"). Similarly, in *Baker Hughes Inc. v. Nalco Co.*, the court found irreparable harm, in part because the plaintiff would suffer damage to its reputation in that the plaintiff would not be able to resume its higher prices without suffering harm to its name and ability to conduct business. 676 F. Supp. 2d 547, 554. *See also Chamberlain Group, Inc. v. Lear Corp.*, 2007 WL 1017751, at *6 (N.D. Ill. Mar. 30, 2007), *rev'd, vacated and remanded on other grounds*, 516 F.3d 1331 (Fed. Cir. 2008) (granting preliminary injunction because the patentee was losing market share, suffering price erosion and straining its relations with customers). As shown above, these same circumstances are present in present case.

4. Loss Of Ability To Raise Capital

Sequenom's ability to attract investment for research and development and expanding operational capacity would be negatively impacted by Aria's market entry. (Welch Decl. ¶ 60-

61.) Sequenom is a public company and its shareholders have invested tens of millions of dollars in the company on the expectation that Sequenom would be afforded exclusive rights to exploit the inventions of the '540 patent. (*Id.* ¶ 60.) In public offerings just since May 2010, investors have purchased shares in Sequenom resulting in net proceeds to the company of $197 million. (*Id.*) Sequenom expects that its investment in the ongoing launch of MaterniT21 will exceed an additional $70 million dollars in 2012, and some market analysts project the costs for the ongoing launch will be on the order of $100 million in 2012. (*Id.* ¶¶ 42-43). Dr. Rao's analysis shows that "Sequenom will have to raise significant additional capital in order to continue to fund its operations." (Rao Decl. ¶ 42.) Dr. Rao concludes that "[g]iven that Sequenom cannot self-fund through its operating cash flow (and this cash flow will be further reduced by the launch of a competing, infringing product), its very survival is dependent on being able to raise additional capital." (*Id.* ¶ 44.) Sequenom's ability to raise capital would be diminished by Aria's entry in the market with its infringing test. (*Id.* ¶ 45.) The loss of revenue and diminished capacity to raise capital would force Sequenom to reduce its operating expenses, including reducing the number of sales force personnel and halting facilities build-outs and improvements. (Welch Decl. ¶ 61.) *See Sanofi*, 470 F.3d at 1381 (noting potential layoffs as irreparable harm to patentee).

5. Aria's Marketing Approach Is Likely To Spoil The Market

If Aria puts an inferior service on the market, or if it markets its service "off label" for uses that are not supported by clinical data – by, for instance, marketing its Harmony Prenatal Test to women with low risk of fetal aneuploidy pregnancies – Aria will poison the market and irreparably harm Sequenom's opportunity to create and exploit a sustainable market. (Welch Decl. ¶ 59.) Aria's promotional material for its Harmony Prenatal Test does not limit the test to women in the high risk group, and presumably Aria intends to make its test available to the low-risk group. This will harm the market. (Evans Decl. ¶¶ 147-155.) Dr. Evans concludes that "[i]f Aria is permitted to market the Harmony Prenatal Test™ at all, *i.e.*, if it is not enjoined, and if it markets the test to women with low risk of fetal aneuploidy pregnancies without a proper clinical validation, it will significantly harm the market for noninvasive aneuploidy testing." (*Id.* ¶ 155.)

See P.N.A. Const. Techs., Inc. v. McTech Group, Inc., 414 F. Supp. 2d 1228, 1243 (N.D. Ga. 2006) (finding that problems with an infringing product can adversely affect a patentee's sales).

6. Aria's Financial Inability To Satisfy Judgment

As shown above, it is clear that an award of damages could not fully compensate Sequenom for the likely harms it will suffer in the absence of a preliminary injunction. That would be the case even if Aria had the financial wherewithal to satisfy a damages award upon a final determination. But here, the inadequacy of a damages award is heightened further by the prospect that Aria would not be financially capable of satisfying a damages award. (Welch Decl. ¶¶ 57-58; Rao Decl. ¶¶ 46-48.) The risk that an accused infringer may not be able to satisfy a damages award weighs in favor of injunctive relief. *See, e.g.*, *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1154 (Fed. Cir. 2011) (infringer posed a "[m]oderate risk of severe financial stress, such a[s] bankruptcy, over the next 12 months"); *QBAS Co., Ltd. v. C Walters Intercoastal Corp.*, No. SACV 10-406, 2010 WL 7785955, *12-*13 (C.D. Cal. 2010) (noting infringer's "precarious financial position"); *Kimberly-Clark Worldwide, Inc.*, 714 F. Supp. 2d at 936 (holding that preliminary injunction appropriate where an infringer fails to present adequate evidence of its ability to pay a damages judgment).

C. The Balance Of Equities Tips Decidedly In Sequenom's Favor

As shown above, the harm Sequenom would likely suffer if Aria is not preliminarily enjoined is irreparable and could not be remedied after trial. Sequenom "may not recoup all of its 'significant investment' in both time and resources spent developing and safeguarding its intellectual property." *Finjan Software, Ltd. v. Secure Computing Corp.*, 2009 WL 2524495, at *11 (D. Del. Aug. 18, 2009) (finding that the balance of hardships favored the patentee as it would not gain the value of its investment in its patents without a permanent injunction). Aria, however, has no basis to complain that it would lose sales if it were enjoined. "Simply put, an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). As the Federal Circuit has reiterated, "'[o]ne who elects to build a business on a product

found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.'" *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683,704 (Fed. Cir. 2008) (citation omitted). The impact an injunction may have on others is irrelevant: "the balance [of hardships] considered is only between a plaintiff and a defendant." *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1330 (Fed. Cir. 2008).

D. The Public Interest Favors Entry Of A Preliminary Injunction

The Federal Circuit has long acknowledged "the importance of the patent system in encouraging innovation," and, more specifically, that the "encouragement of investment-based risk is the fundamental purpose of the patent grant, ***and is based directly on the right to exclude***." *Sanofi*, 470 F.3d at 1383 n.9 (upholding preliminary injunction, noting investment by innovator was incentivized by patent system) (emphasis added). Denying a patent holder an injunction would do the exact opposite – discourage investment in innovative technologies. Accordingly, only "in rare instances" have courts "exercised their discretion to deny injunctive relief in order to protect the public interest." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995).

In *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 707 (D.N.J. 2000), the court found that the public interest weighed in favor of an injunction, in part because the patentee could meet the demand for vaccines caused by the withdrawal of the infringer. *See also Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1309 (N.D. Ill. 1991) (granting preliminary injunction where the patentee could supply the total market with its needs). So too, here, Sequenom has the capacity to meet the entire projected market demand, and is actively building capacity to accommodate for potential market growth. (Welch Decl. ¶ 26.)

Courts have rejected the suggestion that the lower cost of a product is a public interest factor counseling against an injunction. "[S]elling a lower priced product does not justify infringing a patent." *Pfizer*, 429 F.3d at 1382 (citation and internal quotation marks omitted). As the court in *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 581 F. Supp. 2d 160, 226-27 (D. Mass. 2008), *vacated in part on other grounds*, stated:

> If the Court allowed Roche to introduce MIRCERA into the market, perhaps a few patients would benefit, and maybe Medicare would save a few dollars. These arguments, however, could be made for almost any infringing drug. . . .

> By contrast, granting injunctions encourages companies to devote their energies toward developing drugs that will satisfy unmet medical needs.

That analysis applies here. Sequenom developed the MaterniT21 test at great expense in reliance on its exclusive rights in the '540 patent. The public interest is harmed, not helped, by Aria's introduction of an infringing test at a lower price point: lower cost products do not "outweigh protection of plaintiffs' patent rights, in which they have invested talent, time and money . . . Granting preliminary injunctive relief in this matter will serve the public interest and will not unduly stifle competition." *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, No. 11-11681, 2011 WL 5114475, at *13 (D. Mass. Oct. 28, 2011).

III. CONCLUSION

For the foregoing reasons, Sequenom respectfully requests the entry of an order preliminarily enjoining Aria from infringing the '540 patent.

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Respectfully submitted,

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